IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and all others similarly situated,	:	CIVIL ACTION
Plaintiff	:	
vs.	:	
ZENECA, INC; and ASTRAZENECA PHARMACEUTICALS, L.P.,	:	
Defendants	:	NO. 04-135 (SLR)

- - -

Wilmington, Delaware
Friday, September 9, 2005
10:00 o'clock, a.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge

- - -

APPEARANCES:

CHIMICLES & TIKELLIS LLP
BY: A. ZACHARY NAYLOR, ESQ.

-and-

SPECTOR, ROSEMAN & KODROFF, P.C.
BY: JEFFREY L. KODROFF, ESQ.

-and-

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Official Court Reporter

APPEARANCES (Continued):

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BY: THOMAS M. SOBOL, ESQ.
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Counsel for Defendants

PROCEEDINGS

(Proceedings commenced in the courtroom, beginning at 10:00 a.m.)

THE COURT: Good morning.

(Counsel respond, "Good morning, your Honor.")

THE COURT: Mr. Blumenfeld, I feel like you live here over the last few days. In any event, why don't we make some introductions, and then it's defendants motion, so defendant should proceed.

MR. SOBOL: Good morning, your Honor.

THE COURT: Good morning.

MR. SOBOL: My name is Tom Sobol. I'm with Hagens Berman Sobol Shapiro, for the plaintiffs.

MR. HADDAD: Good morning, your Honor. Go ahead.

MR. GOLDSER: Good morning, your Honor. Ron Goldser. I'm from the Zimmerman Reed firm in Minneapolis, also for plaintiffs, and my client in particular is Linda Walters.

THE COURT: Thank you.

MR. KODROFF: Good morning, your Honor. Jeffrey Kodross, Spector, Roseman & Kodroff, Pennsylvania Employees Benefit Trust Fund.

MR. McDONALD: Good morning, your Honor. Christopher McDonald, on behalf of plaintiffs. In particular Walters.

THE COURT: All right. Thank you very much.

MR. NAYLOR: Good morning, your Honor. Zachary Naylor, Chimicles & Tikellis, liaison counsel for all plaintiffs.

THE COURT: All right. Thank you.

MS. MERIWETHER: Good morning, your Honor. Ellen Meriwether, from Miller Faucher and Cafferty, on behalf of all plaintiffs, and particularly my client is Joe Macklin.

THE COURT: All right. Thank you.

MR. HADDAD: Good morning, your Honor. I am Mark Haddad, from Sidley Austin Brown & Wood, for the defendants.

MR. BLUMENFELD: Good morning, your Honor. Nice to be here again.

THE COURT: I'm sure.

MR. SCAGGS: Good morning, your Honor. R.J. Scaggs.

MS. HASKINS: Good morning, your Honor. Natalie Haskins, from Morris Nichols.

THE COURT: All right. Thank you very much,

counsel.

Why don't we have defendants' counsel begin on their motion.

MR. HADDAD: Thank you very much, your Honor.

What I'd like to do this morning, if I may, is spend just a few brief moments on the injury and causation issues and then spend the bulk of my time on the preemption issues.

With respect to injury and causation, AstraZeneca has a straightforward submission here. We say that at a minimum to plead a valid complaint, plaintiffs have to plead the elements of the economic loss claim that they are bringing. And for each of the plaintiffs, they failed to plead the rudiments of either economic injury and loss or a causal link between such loss and the conduct they are complaining about.

With respect to the individuals, this is particularly stark. We have four individual plaintiffs, one of whom alleges that he purchased Nexium for his personal use and the other three who allege that they paid co-payments for Nexium. That is where the allegations begin and that is where they end.

There is no further allegation about what they would have purchased or been prescribed by their physician if they hadn't been prescribed Nexium. There's no allegation of

what they would have paid for whatever this other medication would have been if it had not been Nexium. And this is just a stark example of no -- only giving you one-half of the equation, if you will. We know that they paid something, but we don't know what they would have paid in the alternative.

With respect to the causation element, we don't know in particular whether there is any relationship between the advertising and the prescription that each of these individual plaintiffs received. We don't know what each of these plaintiff's physicians would have done but for the conduct that is being challenged here.

There are a number of other PTIs in the marketplace. Which one would these plaintiffs have gotten? They don't allege what their physicians would have done but for the ads. They don't allege that their physicians were misled by the ads. They don't allege that their physicians saw the ads. For that matter, they don't allege that they themselves saw the ads.

So there is a complete disconnect, in other words, in the complaint between the experiences of these four plaintiffs, individual plaintiffs, and the conduct that they are complaining about.

Plaintiffs have attempted to overcome this by generic allegations at the back of their complaint that

hundreds of thousands of people have been misled and so forth, but we submit that what happened allegedly to hundreds of thousands of individuals has no bearing and does not tell us anything about what happened to these four plaintiffs. We need to know what their factual allegations are of their personal injury and their causal link to the conduct before we know whether they have alleged facts that, if they can prove them, would establish the elements of these claims.

So it's a pleading issue that we think is a threshold and significant issue for the individuals. A fortiari plaintiffs, and there are three of those, there is no injury or causation pleaded. The associations have alleged no injury of any kind to themselves. They purport to plead the case of their individual members, but they cannot seek damages for their individual members and they have not attempted to make the kind of elementary pleadings of economic loss and causation for their individual members that would allow them to seek injunctive relief, which is the most they could conceivably seek.

That leaves just the three third-party payers. And, again, the complaint is just empty of any factual allegations that would either establish a concrete claim of economic loss or that would link the ads to the reimbursement that these third-party payers allege they

made for Nexium.

There's no allegation that anybody at the third-party payers saw any of these ads, made a decision based on these ads, or that the physicians, again, that prescribed the Nexium to the beneficiaries to the third-party payers relied on these ads.

So, again, we're not saying that they couldn't make allegations that would satisfy the elements. We're just saying that they have not and that they need to for the Court to know and for us to know whether they have plaintiffs that can establish standing under Article 3.

We think that the case that is closest to this one on these issues is the New Jersey Citizen Action Case versus Schering-Plough. That's a case that we've cited in our papers. It's a case in which a very similar group of individuals and public interest organizations sued the manufacture of Claritin, saying that the ads for Claritin overstated the benefits of Claritin, made it seem as if, you know, the world would be a much better place for all of these patients if they would just take Claritin, and the theory of the complaint was it wildly overstates the benefits, and there are all these people in America who shouldn't be taking Claritin and who are overpaying for it.

And the Court just said, Look, without allegations of causation, even though in New Jersey,

for example, as in Delaware, there's no element of reliance that's required under the Fraud Act, there is an element of causation. And the Court dismissed the claim on the pleadings in part because there were simply no allegations that could meet the causation requirement.

So those are our essential positions with respect to injury and causation.

We think that they require, at a minimum, that the Court dismiss the complaint and understand that, typically, an opportunity would be given to replead, although we have to note that these plaintiffs have pleaded their case in some instances more than once.

But I think the more fundamental question that I wanted to spend a little bit more time on this morning is, Is there a viable complaint here at all on the merits? Can these plaintiffs litigate the essential claim that they want to bring?

And here, your Honor, we submit that they cannot. We submit that there is a huge problem on the merits of their case that prevents them from going forward with the case that they want to bring and that they cannot plead around. And the huge problem is that what they want to challenge is really not advertising, it's agency action. It's a decision by the Food & Drug Administration to approve Nexium as a new drug and to approve in particular

a 40-milligram dose of Nexium for the healing of erosive esophagitis.

The significance of that is this: By approving a 40-milligram dose of Nexium for healing erosive esophagitis, the FDA relied upon and necessarily found that the studies that plaintiffs want to say are skewed and slanted in their words are, in fact, adequate and well-controlled studies to the point that the FDA approved summaries of these studies on the label that appears necessarily by law covers every prescription of Nexium, and the FDA approved in particular the 40-milligram dose in comparison to both 20-milligram doses of Nexium and 20-milligram doses of Prilosec, 20 milligrams of Prilosec being the maximum recommended dose for the same indication of healing erosive esophagitis.

And when one looks at the labeling of Prilosec, one sees that not only is 20 milligrams the maximum dose of Prilosec, but the FDA declined to recommend a 40-milligram dose of Prilosec.

So what plaintiffs want to argue is a, in their words, a game, quote unquote, being played on American consumers is, in fact, the product of an exhaustive, deliberative agency process committed to the Federal Food & Drug Administration by Congress to, in effect, to, in fact, approve these different dosages with their different levels

of effectiveness of these two drugs?

To see how stark this is, I would like, if I may, to hand up to the Court a copy of our request for judicial notice, which is unopposed and which contains the two critical labels here for our argument, the Prilosec and Nexium label.

THE COURT: All right.

(Mr. Haddad handed documents to the Court.)

MR. HADDAD: Your Honor, I have, to facilitate matters, I have put numbered tabs on the copies.

THE COURT: All right. And I might hand back the second copy you gave me, but I will do that later.

MR. HADDAD: Okay. I didn't know if a law clerk or someone would want that.

The second of the two exhibits in our request for judicial notice is the Prilosec label. And what you will see tabbed as Tab 1 is Page 24 of the Prilosec label. And that is the part of the Prilosec labeling that refers to the dosage and administration that the FDA approves for each of the different indications. And highlighted at the bottom of Page 24 is the recommended adult oral dose for the treatment of patients with symptomatic GERD, and then continuing on 25, the recommended dose for patients with erosive esophagitis due to GERD. And in each case, that dose is 20 milligrams per day.

And if you turn to Tab No. 2, which is on Page 2 of the labeling, you see the discussion of the studies that support the dosage for erosive esophagitis, and there you find a summary of the study that the FDA concluded did not show that 40 milligrams of Prilosec was more effective than 20 milligrams, and therefore led the FDA not to approve a dosage of 40 milligrams of Prilosec.

Now, the stark comparison and really the core of the case is when you look at the Nexium labeling, which is Exhibit 1, and, in particular, look at Tab 3, if you would.

Tab 3 has the corresponding recommended adult dosage for Nexium, and the Court will see that the FDA approved both 20 and 40 milligrams of Nexium for the same indication of the healing of erosive esophagitis.

And turning, then, to Tab 4, which begins at Page 13, here we have the clinical studies on which the approved doses were based. And these studies show to the FDA's satisfaction that it is appropriate to approve and to prescribe a 40-miligram dose of Nexium for the healing of erosive esophagitis.

And, in particular, it is Studies No. 2 and No. 4 which are summarized here that show a significant difference in the effectiveness of Nexium as opposed to Omeprazole, which is the generic name for Prilosec.

Study 2, for example, showed that at Week 4, the percentage of patients that were healed on a regimen of Nexium and 40 milligrams was 75.9 percent whereas only 64.7 percent of the patients who were taking Prilosec at 20 milligrams were similarly healed.

And your Honor can look at the similar comparisons for Week 8 for Study 2 and, of course, for Study No. 4 with that same comparison of the maximum approved dose of Nexium at 40 and the maximum approved dose of Omeprazole at 20.

Now, this table compared the studies that looked at the hearing of the condition of erosive esophagitis of the erosions in the esophagus. Table 2 measured a different aspect. This is how long it took to get to what the studies defined as the sustained resolution of heartburn symptoms. And, again, Studies 2 and 4 showed that Nexium was significantly more effective than, at its maximum dose of 40 milligrams than was Omeprazole or Prilosec.

So what plaintiffs want to call a game is, in fact, the FDA's decision to recognize that Nexium at 40 milligrams is more effective at healing erosions in the esophagus and at producing sustained resolution of heartburn symptoms for patients with erosive esophagitis than Prilosec at its maximum dose of 20 milligrams.

And our fundamental position is that if

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plaintiffs want to bring a lawsuit challenging the so-called game about skewed studies or dosages, that is a complaint they have to bring to the FDA or to Congress, but not to a federal or state court.

Now, I think it would be helpful to look at the implications for the particular allegations and claims that plaintiffs have made about the ads here because I think with this basis in the record, I think we can see that the ads that they are attempting to challenge are all variations on a theme that is trying to attack agency action.

Our fundamental position, and I don't think plaintiffs -- plaintiffs certainly have not contested this. Whether they would say they concede it, I don't know, but they seem to accept the framework that I'm about to propose at Pages 1 to 2 and 25 of their opposition.

But, in any event, we think the basic framework is plain. You have to look at the ads they are challenging in light of the labeling that the FDA has approved. The labeling creates a basic federally approved framework for the types of statements that a manufacturer can make about a prescription drug.

Now, if the manufacturer goes outside the label, makes claims that aren't supported by the label, then state law can provide a remedy. If a manufacturer omits an important warning that relates to health and safety, Courts

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have held that that kind of claim isn't preempted. But that's not what we have here. We have advertising statements that are supported by and are consistent with the labeling, and in those situations, there is no cause of action. There is certainly no cause of action under Delaware law because Delaware law, the Delaware Consumer Fraud Act, expressly creates a safe harbor and accepts advertising that complies with federal law as administered by the FTC.

And that's, I think, Section 2513(b) of the Delaware Consumer Fraud Act. And the case that is most on point here is the Seventh Circuit's decision in Bober, B-o-b-e-r. Bober is another double-dose case that was dismissed on the pleadings and affirmed by the Seventh Circuit. And there as here, the essential claim was that the manufacturer was misleading the plaintiff and the class that was alleged, thereby failing to tell them that they could take two doses of the over the counter product Zantac, 75 milligrams, and get the same benefit as if they took the more expensive single prescription dose of 150 milligrams of Zantac.

And the Seventh Circuit affirmed the dismissal of that case on the pleadings. The Court noted that 75 milligrams of Zantac over the counter was a different drug under federal regulation than 150 milligrams of Zantac prescription. There had been no studies to show whether 75

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milligrams over the counter was the same as 150. The manufacturer could not recommend or suggest that two doses of Zantac 75 were the same. That was not permitted under federal law.

So the omission that was the heart of the Bober case simply wasn't within the realm of what the company could do under the federal framework. They were complying with the federal framework by separately advertising their products and, therefore, there was no liability, no case could go forward.

The same is true here. I think we have a more compelling case, frankly, than Bober. Here, the critical omission that they allege throughout to attack all of the ads is an alleged failure on AstraZeneca's part to say that the "exact same relief" is available with Prilosec.

And omission theory is critical to their case, by the way, because they want to attack the entire direct-to-consumer advertising campaign. They want to say that AstraZeneca built up an entire market for its product with every ad and so the critical way they want to do that is through an omission theory. Every ad failed to say that there's another AstraZeneca product that's exactly the same, provides the exact same relief, that's just as good, et cetera.

Now, that is not something under federal law that

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the FDA would permit AstraZeneca to say. It can't be said even on the allegations of this complaint.

The plaintiffs acknowledge, and they have to, that on the labeling as shown, there is a difference between the recommended dose of Nexium at 40 milligrams and the maximum recommended dose of Prilosec at 20 milligrams. There is a clear difference shown on the labeling, supporting the different dosages, in terms of the effectiveness of Nexium at 40 milligrams, at healing and relieving the symptoms of erosive esophagitis.

And if you look at Paragraph 77 of the complaint, you will see plaintiffs' fundamental answer to this problem. They say, Well, the logical conclusion to draw from all of these studies is you should have, AstraZeneca should have doubled the dose of Prilosec and forgotten all about the new purple pill, Nexium.

Well, it's an interesting argument, but it does not support an advertising campaign. There is no approved double dose of Prilosec. That has not been approved by the FDA. There is no study showing that a double dose of Prilosec is the same as Nexium.

AstraZeneca would violate its obligations as the FDA has set them forth if it were to argue or even suggest or recommend in its ads that patients take a double dose of Prilosec. And we have cited the statutory, regulatory

authority and examples of the warning letters that are publicly available on the FDA's website that are the precursors to enforcement action that routinely occur when companies try to recommend an unapproved dose.

So this omission theory just has no legal foundation. It does not state a claim under Delaware law, and even if there were Delaware or other state law that would allow a claim like this to go forward, it would be preempted under basic conflict preemption principles because state law cannot require a disclosure that federal law prohibits.

Once we put this omission theory to one side, there's very little left of their complaint. I think, broadly speaking, we can look at two categories of claims they want to make and try to make.

They -- the first category would be misstatements. They have pointed to certain factual statements in some of these ads. They've pointed to, for example, the statement that Nexium is the number one PPI recommended by gastroenterologists or that more patients have been switched to Nexium than to any other PPI.

Well, those are factual statements, but what's very significant about those statements is plaintiffs do not allege that they are false. They do not allege that Nexium is not or was not the number one PPI recommended by gastroenterologists at the time the statement was made. They

don't claim that they can prove that more patients were switched to some other PPI than to Nexium.

They just claim that statements like this create by implication an aura that somehow Nexium is better than Prilosec, and they think that that sort of aura or implication is misleading.

Our position is that the same implication necessarily would follow from the labeling. If AstraZeneca, for example, republished the excerpt of the labeling that we looked at in Exhibit 1 to the request for judicial notice, the Nexium labeling a moment ago, plaintiffs would contend that that also carries with it an implication that Nexium is better than Prilosec. They have said in their complaint, they have alleged that by doing the studies in the way AstraZeneca did, we skewed and slanted those studies to create a misleading implication of superiority.

The very same implication of superiority that plaintiffs claim to be able to find in the ads they challenge is right there on the label by the very terms of the their own complaint. It's not, by the way, to say that we are arguing that there could never be a claim of superiority outside the labeling if there were comparative statements that Nexium is -- works 50 times faster than Prilosec. That's not on the labeling and that's a factual assertion and that could be tested in a

court of law to see if it was true. But that's not what's here in the ads.

As the Court goes through the ads, the Court will see, there's not a single comparative statement overtly of that nature at all. It's all implications. It's all lurking between the lines, allegedly what someone would draw from these factual statements that they cannot and do not contest were false. And so our position is we are permitted to make those factual statements because they are consistent with the label, and by necessity any implications that arise from statements that are consistent with the label are -- are there in both the labeling and in the ads.

I expect that the plaintiffs may want to point to certain ads, and if they do, we can look at whichever particular ads they wish to highlight this morning and perhaps in response I can look at those.

But I think if the Court looks just at one example, it would be Paragraph 130 of the complaint, the Court will see an example of just how lacking in substance the claims of misleading ads are.

The upshot of all of this, your Honor, is this: Plaintiffs want to embark on a very profound lawsuit. They want to take up the challenge essentially to the entire practice of direct-to-consumer advertising of this new product.

In their view, as they allege it in the complaint, Nexium should never have been brought on the market. It was a mistake for the FDA to approve it, a mistake for AstraZeneca to seek approval for it. In their view, the studies, if properly done, would have shown no benefit to Nexium. In their view, the studies properly understood today show no benefit, and in their view, this is a product that cannot be advertised unless it's accompanied by disclaimers that say other products including our own are just as good and cheaper.

That is not a valid basis for attacking commercial speech. It's not a valid basis for attacking a prescription drug because it changes, in effect, the standards that Congress and the FDA have set for the approval of new drugs. And, frankly, it trenches on basic commercial speech protections. There's no obligation to advertise about other drugs. If what you say about the drug that you manufacture is fair and within the labeling, then your ad is permissible. And if someone else wants to talk about other drugs, other dosages, the marketplace is open to them.

The state has ways of communicating. Congress and the FDA are available for policy debates about the standards on which drugs should be approved. But state unfair competition laws and common law do not exist to stifle that speech.

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Thank you.
THE COURT: Thank you very much.
MR. HADDAD: Thank you, your Honor.
MR. SOBOL: Good morning, your Honor.
THE COURT: Good morning.
MR. SOBOL: May it please the Court, Tom Sobol for plaintiffs, your Honor. It's a pleasure to be here and thank you for the Court's patience and time.
I think it's important for me to start at the outset, your Honor, by putting a more accurate framework on the allegations of the complaint that is before you because, with all due respect to Mr. Haddad, there seems to be a really fundamental misunderstanding about some of the core allegations of the complaint as they really differ from some of the statements that have been made.
So I would just -- just for a couple of moments put that in the right framework.
Of course, a very simple procedural context in 12(b)(6), the allegations of the complaint control, and I will also deal with some of the specific issues of the regulations and the approval labeling Mr. Haddad has pointed to.
But this case arises when AstraZeneca saw the likelihood obviously of generic entry for its brand name Prilosec and was trying to do and explore,

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understandably, legitimate business objectives to try to figure out a way to either continue on with the brand-name position coming in with some alternative product. As a result, among the things that it did, it explored the possibility of trying to come up with a better drug. Eventually that would be called Nexium.
They explored that through scientific effort. Then they explored it through clinical studies. And when they went through those studies, then they sought approval for the drug, too.
AstraZeneca's effort before the FDA was in large part to seek to have the FDA approve Nexium as better than Prilosec. And the allegations of the complaint state that there were 11 studies that were before the FDA. Only four of them were comparative studies. Seven of them were basically seeking to get Nexium approved as better than a placebo, i.e., as better than nothing.
The allegations of the complaint control and also through quotes from the FDA itself, the FDA approved Nexium because it was better than a placebo. It was better than nothing. And that is the only basis upon which the FDA approved Nexium to be able to be marketed, sold, for esophagitis and for GERD.
Now, in the context of that iterative process between AstraZeneca and the FDA, AstraZeneca was trying to

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get the FDA to do more than simply approve Nexium as better than a placebo. The sponsor sought to get the FDA to agree with them, the sponsor being AstraZeneca, of course, that Nexium was better than Prilosec, and submitted to the FDA the same studies that Mr. Haddad and other information that I can identify for you today. There was other information also behind -- before the FDA at that time.
The FDA did undertake a very exhaustive, thorough process, and refused, unequivocally, and on multiple occasions, to agree with the sponsor's request that it be able to make representations that Nexium was better than Prilosec. It failed in the fundamental mission of what they were trying to do with this product.
The allegations of the complaint, then, cite on various occasions -- I have a hand out here, if I may, your Honor.
May I approach?
THE COURT: Yes.
(Mr. Sobol handed documents to the Court.)
MR. SOBOL: If, your Honor, you could turn to Page 7 of the handout, these are allegations in the complaint, but we're also referring to aspects of the FDA's thorough and deliberative process when they rejected AstraZeneca's effort as sponsor for Nexium to seek to get a superiority claim for Nexium.

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Paragraph 65. A superiority claim of Nexium over Omeprazole, that's the generic Prilosec, is not supported by either the comparison to the 20 milligram or to the 40 milligram. I'm obviously paraphrasing here.
Elsewhere in the complaint, your Honor, regarding the treatment of symptomatic GERD, claims of superiority of Nexium to the Omeprazole are, once again, not supported. Neither the 20, nor the 40 milligram dosages, are differentiated from the 20 of Prilosec.
There's another example, your Honor, Paragraph 68 of the complaint, where it's talking about a summary of the benefits and risks of Nexium. Go down toward the bottom of the bolded. Therefore, the sponsors, that's AstraZeneca's, conclusions that Nexium has been shown to provide a significant clinical advance over Prilosec in the first-line treatment of patients with acid-related disorders is not supported by the data.
If you go to the next page, your Honor, on Page 8, I'm going to jump through Paragraph 69 to shorten things up and go to Paragraph 76 of the complaint. The FDA found there are no studies, not some, unequivocally, there are no studies which demonstrate that Nexium is superior to Prilosec clinically or even statistically.
In the 12(b)(6) context, your Honor, those allegations control, and we also think we will be able to

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approve beyond any doubt over time that AstraZeneca's fundamental mission in terms of trying to come up with a product that it could legitimately differentiate as better than Prilosec have failed and that the FDA has rejected that claim of superiority.

Now, if one, then, turns to the labels that Mr. Haddad has pointed to, it is true that there is an approved indication. The approved indication for Nexium is simply that it is to be given, you know, for GERD and for healing esophagitis. There is no -- nowhere in the label is there any statement that it is being approved as better than Prilosec at all, nowhere there. And, indeed, that would be bizarre to be there because the FDA specifically rejected that effort by AstraZeneca.

The FDA, in its labeling, can permit a sponsor, when they are drafting the label, as a sponsor drafts the label and submits it to the FDA, the FDA reviews it, it is optional, if you go to Mr. Haddad's Tab 4, if one wishes on a topic, and I think the regulations say it may be on a nonessential, but it may be an important, you know, topic. One can put in clinical studies to provide information to clinicians.

Now, here, what the label does is simply provide some of the raw data. In other words, these -- this statement of clinical studies, there is nowhere on these two

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pages or anywhere else of what the FDA's conclusion is about the data or analysis of the data. There's no discussion about it at all. And, indeed, if one goes back into the FDA proceedings and the efforts by the sponsor repeatedly to try to get the FDA to give them the superiority claim that the FDA rejected, this is precisely some, not all of the data that the FDA rejected as affording AstraZeneca an ability to have a superiority claim of Nexium over Prilosec.

Indeed, so to say, this is raw data. In other words, your Honor, this data on Page 13 and then Page 14, this does not speak for itself. It requires analysis against this data and the other body of information itself.

One does not have to accept AstraZeneca's interpretation now of this data, and that's what AstraZeneca proposes that we do. In other words, it proposes that this Court come up with the only conceivable interpretation that they think is capable from this data in a 12(b)(6) motion even though the record that the Court must assume, you know, is accurate and which AstraZeneca hasn't disputed that the FDA rejected this interpretation. In fact, concludes the opposite.

Also, I would say, although I'm a layperson, in looking at this, that the endoscopic analysis, that's the first, when you go in, you take a peak. Actually, two of the

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studies showed that there was no significance. Two others have a reasonable P value, but the increases weren't significant.

And if you go to the next one, where you're actually talking about the changes of the symptoms, most of the studies came up with no difference at all and where there are reasonable P values, there are very small differences.

So the bottom line point is, including some data so that practitioners out there in the world can see some of the information and draw some conclusions that they may or may not want to be able to draw on their own does not really have to accept AstraZeneca's interpretation right now on the pleadings. It's not as if we have done this in a cursory way.

I think the complaint goes on in some detail as well as our memorandum that we're drawing on unequivocal statements by the FDA. We're not being cute about it. We're not trying to pull something out of somewhere. We don't have our own expert's opinion about this. We're not trying to have a battle of experts here. We're going precisely to what the FDA has projected that AstraZeneca could do.

And that, then, places in context a response to most of the balance of the argument in terms of preemption because, then going back to placing the case in context,

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AstraZeneca, once it got this formal approval by the FDA, but the rejection of the claim of superiority, had on its hands a product that was no better than the brand name product that was going into generic competition, and it had choices it could do.

Now, it didn't have the ability to differentiate that product as better than Prilosec because that wouldn't be true, and it would be beyond the label of what it is that had been approved by the FDA.

Now, they are businesspeople. They could have made a variety of decisions. They could have said, Well, we'll compete on price. We'll put Nexium out and try to differentiate on the difference of price. They could have put it out and tried to differentiate that from some other different kind of compound. But they did not do those things. They could have said, You know what? This R&D effort failed and it's not worth our effort to go into the market with this additional drug because for us to do that, you know, we don't have a legitimate basis to differentiate.

But it chose something else. It chose, despite the scientific evidence, despite the statements from the FDA saying it's not any better, to go to market anyway, pretending like it's a better drug. And that's what this case is about. What this case is about is that this company

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was not going to listen to it no matter what the evidence showed, what
the science showed or what the FDA told them. They were
going to go off and do it anyway and they did.
They went off, and I will get to this later about
what our allegations show, but they engaged in a broad based,
not only just ads, not just direct-to-consumer advertising,
but also marshaling an Army of 6,000 sales representatives to
go out there and flood doctors' offices with claims of a
superiority of Nexium over Prilosec. And they did that
contrary to what had occurred before, and that's the overall
context of the case. And those what the allegations are,
too.
Also, I would say, your Honor, these are not just
plaintiffs' comments in terms of playing games. Obviously,
we quoted a senior official in the Federal Government, Mr.
Scully, who had two years into or so of the Nexium marketing
effort, himself said this is a game. It's ridiculous. It's
being played on you. It's the same drug. It's no better.
They're charging more for it. It's a game.
These are not things that we've come up with on
our own.
With those allegations, I would then turn to the
preemption argument because, and there have been -- I think
it's always a coupled process. When we have opening brief,
opposition, reply brief and we have argument, the preemption

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issue, although there's a lot of paper written on it before
your Honor, really boils down to one thing. How that boiling
happens is this. We now hear, there's obviously no express
preemption argument then being made, some express argument.
There's no field preemption argument being made. There is no
other argument being made other than this somehow conflicts
with what the FDA has already approved, and that's wrong for
two fundamental reasons.
First, the FDA rejected this claim. They did not
approve this claim. They rejected this claim. And so there
can't be any conflict.
The second thing is that their argument, which
ends up being somewhat of, at least for me a brain twister,
is that, Well, your case, plaintiffs, boils down to
things that we should have said, you know, that we omitted
in saying, and that, therefore, there are other things
you plaintiffs are telling us that we should have been
saying.
That's not -- that's not the argument at all.
We're not saying that they should have been in the market
saying take Prilosec two times a day or take double dosage of
Prilosec. That is not the case at all.
What we are saying is, don't go into the market
and be making comparative claims to Prilosec to begin with.
If you make comparative claims, the only way those things end

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up being true is there's a lot of other information that's
out there. In fact, what it shows is that your fundamental
thing that you are trying to pursue is just wrong.
So they had many other choices other than to
try to have some kind of forced speech or having to say
something about, you know, double-dosing Prilosec or taking
it twice. This is not a double dose case at all. We don't
allege it that way. We don't say it that way. It's not what
this is.
This case instead is a situation where they're
going out and making affirmative statements or omitting to
say things that are directly contrary to what they just have
failed to get from the FDA.
The requirements of conflict preemption are
obviously in the briefs, that kind of thing, but conflict
preemption is probably the most difficult type of preemption
to have. You have to show a very stark, bold requirement
that the case to go forward would require you to do something
directly contrary to what an FDA regulation or, you know,
federal act would be. That's not what this case is about
at all.
When the FDA approves Nexium is better than
placebo, then no one is stopping them from going to market.
They can market their drug. They can sell their drug but
they can't be making comparative claims to Prilosec. And,

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sure, that's going to be limiting, because that's the nature
of the product that you have.
And when it comes to drugs, you can't
differentiate your products by, you know, delivery systems or
service, that kind of thing. It really ends up having to be
the attributes of the drug itself, and they have failed to do
that.
So preemption ultimately does not apply because
there cannot be a conflict in an FDA determination that runs
directly contrary to what they are trying to do. It's just
they -- I would be repetitive on that.
Here, then, given the allegations of the
complaint, as Mr. Haddad indicated, if the ads go beyond,
if the direct-to-consumer advertising goes beyond, if the
detailing and promotional efforts through the 6,000 people
that are out there in the country go beyond the label, and
they are arguably actionable under Consumer Fraud Act, then
they can be -- then they can be sued on. That's precisely
what has occurred here.
The allegations of this complaint show that
through a variety of different methods, direct-to-consumer
advertising and the sales force and the like, what
AstraZeneca did has created the impression, either express by
comparisons to Prilosec or implied by comparisons to Prilosec
or through reinforcement ads, once they had been able to give

the impression that Nexium is better than Prilosec, the continued and repeated drum beat throughout the country in multi-media format that Nexium was better than Prilosec.

I will also point, your Honor, that there's something of a little bit of a twist. We recognize that some of the ads are not completely overt in stating that Nexium is better than Prilosec. But as you know, one does not need that for consumer protection claims. Implied superiority, false and deceptive advertising, is capable of much more broader constructions than the need to be able to parse the text of a particular ad in order to be able to prove a claim that is being made. That's, in fact, the fundamental purpose of having consumer protection laws.

But I will say this: If AstraZeneca really believed that the FDA had approved Nexium as better than Prilosec, their ads would be singing that like a brass band, and they don't because they know that the FDA didn't approve it for that, and that's why their ads have to be far -- an effort at being more subtle than making that complete overt statement.

And this is not a point to be taken lightly. If you're in a multi-billion dollar market and you're trying to differentiate the new brand-name drug from the old brand-name drug and you really believe that the FDA has said it's superior, it makes no economic sense for a company like

this not to be saying that in absolutely overt explicit language in quotes to the FDA and the like. But they didn't do that because they know, again, that's not what the FDA did. The FDA actually did the opposite and that, therefore, their game, Tom Scully's words, was going to be a bit more subtle, and what they were going to do was make the superiority claims, but do it in ways that don't end up necessarily being overt.

Several times AstraZeneca has argued that you have to look at the ads in the complaint. And I just want to say that there are ads in the complaint, but there are also examples. They're not all the ads, obviously, and there are other allegations in the complaint that talk about and make allegations regarding claims of superiority.

In addition, again, the case is not limited just to the ads. It's also a broad-based promotional effort as well that they had spent hundreds of millions of dollars on as well.

So, again, I don't think it's appropriate just to focus on the discrete number of ads.

So before I move away, then, from the preemption argument, which sort of wraps up many of the points that I was talking about here, this case does not attack the entire practice of direct-to-consumer advertising for Nexium, though it does attack AstraZeneca's effort through a broad-based

campaign to differentiate Nexium as better than Prilosec when the evidence, signs and the FDA say it's not.

They say that, Well, our argument must be that it never should have been brought to the market. That's not our argument. You have to bring your product to the market without making false and deceptive statements about it, and here, AstraZeneca was in its own perception of a predicament because it wanted to make billions of dollars on a product that was not deserving of making a billion dollars on.

They say our case is, our view is that it was a mistake for the FDA to have approved the product. That is not our case at all. There's no allegation, there's no suggestion at all that we think that the FDA made a mistake in approving the product. The FDA can approve many, many products and some of those products will be better than preceding products that are on the market. Sometimes those products will be as good as products in the market. Sometimes those products may even be inferior to products that are on the market.

The FDA's job is to look at the efficacy and safety of the product, and if it satisfies that by placebo, the product goes on the market.

There's nothing wrong with Nexium having been approved. What's wrong here, again, what we said in the complaint is having gotten it approved but having the

superiority claim rejected, you can't go out and try to differentiate your product as better. It's just not the case.

And so this isn't a case where there's some kind of effort to trample on commercial speech that has in some way been sanctioned by the Federal Government. Quite the contrary. It's the classic exercise of consumer fraud laws to protect consumers from false and misleading advertising, and really that's it.

THE COURT: And when you say that, we're talking about consumers and we're kind of ignoring the filter of the expert that stands between the drug company and the consumer, the doctor who theoretically --

MR. SOBOL: No. I don't think it ignores the doctor at all. In fact, it recognizes and the complaint alleges that not only did AstraZeneca make its false and deceptive statements to consumers, but it also made them to doctors. And so -- and did it in quite an extraordinary way because those 6,000 sales representatives aren't going out and making representations to, you know, consumers. They're going out and they're flooding doctors' offices, trying to convince them to use Nexium.

And the other thing, too, by the way, is that, when you have a learned intermediary, of course, you'd want to have a learned intermediary, the primary purpose of the

learned intermediary's role is to protect the safety and efficacy of the product. It's not necessarily to say that Nexium is the same as Prilosec, so you should be taking Prilosec because it might be cheaper.

There's no suggestion made by the plaintiffs, by AstraZeneca in this case, that the role of doctors or that the role that the learned intermediary doctrine plays is that the learned intermediary is also protecting the pocketbooks of the consumer or the consumer's insureds. And as a result, and I think there are other issues that could be raised in terms of the learned intermediary doctrine, too.

Some Courts, like the Perez court in New Jersey indicated that, you know, if you have direct-to-consumer advertising, the role of the learned intermediary doctrine is eviscerated quite considerably because you now have the manufacturer going directly to the consumer to try to influence consumer choice and to try to influence consumer dialogue with the doctor itself, too.

So for all of those reasons, probably the most primary, of course, is that the allegations of the complaint indicate that the false and deceptive advertising campaign is itself being practiced directly on the doctors themselves, learned learned intermediary doctrine wouldn't apply.

Turning, then, to the injury and causation issues, the injury here is really, you know, it's a very

quite simple injury. I'm going to give you another example of a normal Consumer Protection Act case.

If I go into a store and I buy a carpet and I'm lied to regarding the qualities of the product, the carpet salesperson doesn't have as a defense, Well, you know, what kind of carpet would you have bought, Mr. Sobol? Would you have gone down the street and bought a fancier, you know, carpet or a poorer product or something like that?

AstraZeneca's notion here that the allegations must prove a hypothetical which is that which every individual would otherwise have done in terms of which other pill they would have purchased is irrelevant.

Here, the case is that each of the class members that have made the allegations of this in this complaint have alleged that they purchased a product and that they paid too much for it or they wouldn't have bought it at all.

And it's a very classic situation where if you go in and you are lied to or if there's a deceptive act or practice that occurs, that there ends up being damage.

Now, here, it's even more persuasive because here, this is Consumer Protection Act claim under the Delaware Consumer Fraud Act. And one not need prove reliance under the Delaware Consumer Fraud Act. So the notion about whether or not one relied directly or not on this representation is completely irrelevant under the law. What

the law simply requires is that we prove an intent to deceive and the occurrence of an injury. We do not need to prove reliance under the law. And there's an obvious connection because why would somebody be buying a product that has been costing more if there are other ways to get the same kind of treatment elsewhere?

Now, we brief in our case the fact that under Delaware law, there is no reason to be able to prove reliance at all.

AstraZeneca relies heavily on a case, an intermediate appellate court case out of New Jersey by the name of — well, in the Claritin case, but they ignore a more recent New Jersey Supreme Court case that actually assists with this. The more recent New Jersey Supreme Court case is a case called Furst, F-u-r-s-t. I have the cite here. Just a moment, your Honor.

(Pause.)

MR. SOBOL: In -- the first case citation, your Honor, is 182 New Jersey 1, or 868 2nd, 435.

After the intermediate appellate court decision in the Claritin case, the New Jersey Supreme Court case took up a different case in which they discussed what it means to have an ascertainable loss under the New Jersey Consumer Fraud Act.

And there, and the reason I use this carpet

notion, is this: What the New Jersey Supreme Court held is that if you were to buy a carpet at $100 that was really worth $200, could you have bought it for a hundred and it ends up being worth $10, you're entitled to your expectation damages. You're entitled to the difference not between the hundred dollars you spent and the $10 it's worth, but between the $200 that the expectation was, the benefit of the bargain was, of your purchase.

So you get the difference between $200 and $10 under the New Jersey Consumer Fraud Act. And the reason for that, they said, was even if it seems like it might be some kind of windfall, that even in a contract case you'd be able to get your expectation damages.

So in a consumer fraud claim, by definition you should able to get at least what you get in a contract action. They said the purpose is obviously also if the Consumer Fraud Act are remedial and seek to be protective of consumers. They said that's also the amount, by the way, that one would treble under their Consumer Fraud Act. That's what I would consider to be an expansive interpretation, but an accurate one under the Consumer Fraud Act in New Jersey post Claritin.

Here, this case is actually an easier case because the expectation is that when consumers paid for Nexium, they thought they were getting a product that was

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worth that price, but they weren't. They were getting a product that was worth, you know, generic Prilosec.

Here in this case, the bottom line ends up being that the allegations of the complaint indicate that each of the class representatives that are in this case allege that they would not have purchased and would not have spent the money if it had not been the wrongful conduct that had been undertaken by AstraZeneca, and that's sufficient for the Delaware Consumer Fraud Act. It's also sufficient for the unjust enrichment claim.

Your Honor, finally, I want to turn your attention on this causation issue and damage issue to what really should be controlling precedent for this Court. Not controlling, but obviously highly persuasive. It's the decision at the Second Court of Appeals in Desiano on a case that was merely identical. I'm trying to figure out what page of my presentation this is.

If you can go, your Honor, first to Page 18, the hand-out.

As you recall, your Honor, in the Coumadin case that you sat on, while it was an antitrust case, the fact of the matter was that an overcharge in the antitrust context was sufficient for antitrust injury for consumers in that matter. There were also consumer protection claims brought in that case as well.

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What I would suggest, your Honor, is that here, too, the overpayment for a drug that would not have been, that overpayment would not have been made but for the wrongful conduct of the defendant is sufficient injury for the purposes of a consumer protection claim to be able to go forward.

If you then turn to the next page, your Honor, the Second Circuit in Desiano, there's actually a typo there. It should be an O at the end of Desiano. The opinion is really on all fours in terms of the causation here.

Here, the Second Circuit was sitting on the diabetes drug and they considered the hypothetical in which a defendant drug company markets a new, but they put that in quotes, much more expensive drug, claiming that it is a great advancement when, in fact, the company is simply replicating the Metamorphin formula and putting a new label on it.

In other words, the only difference between Metamorphin and the "new" drug is the new name and the higher prescription price, paid almost entirely by the insurance company. In that case, the "new" drug would be exactly as safe and effective as Metamorphin, and thus would be -- there could be no injury to any of the insurance companies' insureds. Nevertheless -- no injury meaning no personal

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injury. Nevertheless, the insureds' companies would be able to claim precisely as they do here, that the defendant engaged in a scheme to defraud it and that the company suffered direct economic losses as a result.

So we suggest, your Honor, that this case, which reversed a grant of a 12(b)(6) motion from the underlying Court, quite clearly is not -- this indication is the hypothetical that the Second Circuit was envisioning there.

And then, finally, your Honor, if you go to Page 20 of the complaint, there have been statements that there isn't a sufficient allegation of causation, that kind of thing.

Again, the complaint is quite, and it's repeatedly throughout the complaint, we end up saying things like, The foregoing advertisement was part of an unfair scheme by AstraZeneca to falsely promote and create demand. The next sentence, The effect of the unfair scheme was to create demand for Nexium where no such demand would have existed had they told the truth.

And then on page -- Paragraph 146 on Page 21, The net effect of this misleading campaign was to establish Nexium in the minds of doctors and consumers as a superior drug for acid relief and as such, to allow it to command a price substantially in excess of generic Prilosec. That and

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other allegations in the complaint indicate that there have been sufficient allegations of causation.

One final observation, your Honor. In one of your decisions, your Honor, in the Coumadin matter, dating back to 1998, where there were 12(b)(6) proceedings involving false and misleading allegations with respect to claims under New York common law, but claims of New York common law that are similar to the Consumer Protection Act claims that are brought here under Delaware law, you wrote, at Page 55 to 56, "In the present case, the plaintiff alleges that due to defendant' false and misleading statements, pharmacy benefit managers, managed care companies and others refused to purchase plaintiff's generic Coumadin. The facts reveal that these entities normally preferred less expensive generic drugs to branded pharmaceuticals. At this stage of the proceedings, plaintiff is entitled to the inference that but for defendants' false and misleading statements, these third parties would have entered into contracts with plaintiff. Plaintiff has presented sufficient factual support to state a claim for relief under common law tortious interference, and the motion to dismiss is denied."

I would argue, your Honor, that, similarly, here, plaintiffs are entitled to the inference under the allegations that we have alleged, under the Delaware Consumer Fraud Act and under unjust enrichment that but for a

widespread, hundreds of millions of dollars spent, thousands of sales representative, all making statements overtly or subliminally or impliedly that Nexium was better than Prilosec, It's the next purple pill, spend your money here, it's going to be better, that under these facts and circumstances, and given the allegations we have regarding the increased sales for Nexium and the like, we're entitled to the inference that but for that conduct, people would have been buying a less expensive product, and, therefore, we're entitled to go forward at this stage of the proceedings.

Thank you.

THE COURT: All right. Thank you.

MR. HADDAD: Your Honor, thank you very much for your time and patience this morning. If I may just respond to a few of the points, I would greatly appreciate it.

I'd like to begin where Mr. Sobol began because I think that his first point really is a good illustration of our fundamental point.

Mr. Sobol began by directing the Court's attention to Pages 7 and 8 of his handout, and Pages 7 and 8 of his handout contain excerpts of several paragraphs of his complaint. And these excerpts are alleged to be portions of an FDA medical reviewer report that accompanied the agency action that was part of the agency's decision.

As the Court will recall, our basic theme

is that what plaintiffs are doing here is attacking agency action, and there is perhaps no more stark evidence of this than plaintiffs' selective use of this medical review or report.

I just want to note two things about it: First, Pages 7 and 8 of selected excerpts stop after Paragraph 76 of the complaint. They don't go on to include Paragraph 79. Paragraph 79 of the complaint is perhaps in hindsight a paragraph plaintiffs wish they did not plead, but in that paragraph, plaintiffs allege that the same FDA medical reviewer recommended a dosage of Nexium of 20 milligrams once a day because this medical reviewer saw, as plaintiffs allege it, no benefit increasing the dose from 20 to 40.

Now, as the Court can tell from the labeling, which is the final agency action, the labeling approves a 40-miligram dose. The labeling is the final agency action. That's what sets the parameters for the scope of advertising. That is the basis, and plaintiffs, I don't hear them challenging this as a legal matter, that tests the framework and the basis for what is permissible as a matter of federal law for AstraZeneca to say.

And we've cited to the Court the Pfizer v. Miles case, where the District Court there similarly rejected a party's attempt to argue on the basis of an accompanying report that was inconsistent with the final agency action.

We have a very simple position despite the complexity and the details that plaintiffs have included in their complaint. Our position is a simple one: That the labeling sets the framework, and this morning I think we've heard Mr. Sobol and the plaintiffs make some important concessions.

Mr. Sobol has essentially, as I heard it, given up on the omission theory that is throughout this complaint. You did not hear him argue that AstraZeneca can be faulted for omitting to tell patients and others in their ads that Prilosec is the exact same as Nexium. As I heard it, that complaint, that argument is abandoned.

We also heard Mr. Sobol say that it's very telling that there's no brass band, I think was his phrase, of music playing the theme that or stating that, trumpeting, I think, that Nexium is better than Prilosec.

And not only is there not a brass band, but there's not a sentence. He has pointed, and his complaint, plaintiffs' complaint has pointed to not one single sentence anywhere in these ads that says that Nexium is better than Prilosec. It's not there to be found. They have attached a dozen print ads. They've quoted from four different television advertisements.

He says, Well, this is not the universe. Well, okay, it's not the universe, but they've had several times to

plead this case. They cannot find a single ad that contains the comparative statement that they say we can't make.

The thrust of Mr. Sobol's presentation this morning was that the FDA did not say on the labeling that Nexium is better than Prilosec. Well, that's fine. AstraZeneca doesn't say in the ads that Nexium is better than Prilosec.

What plaintiffs want to litigate instead are implications, and if the Court would look, for example, at Paragraph 120 and 121, that is where plaintiffs in their complaint summarize what they think is wrong with the television ads. And I think it's illustrative to see how empty plaintiffs' claims that AstraZeneca could have advertised Nexium properly are.

Plaintiffs say that these are the key themes and phrases, this is their words, in television advertisements during the class period. These are the claims that they say are misleading. "Talk to your doctor about Nexium. One prescription daily, heartburn goes away and stays away. Heals erosion in esophagus. Across America, doctors who specialize in acid reflux disease have switched more patients to Nexium than any other prescription of its kind. For many, 24-hour heartburn relief."

These are the themes that they say are the key themes. I've just read all of them from Paragraph 120.

They claim that these are all deceptive statements. Our position is if we cannot make these statements, if we cannot say that Nexium is new, even though the FTC and the FDA expressly have guidance that permit the use of the word "new" in advertising for the first six months after a product is approved as new, if we cannot make the statements that we did make, how are we supposed to advertise this product at all?

They have come into court with a frontal assault on everything that AstraZeneca said, whether it referred to Prilosec or not. They have not attacked, because they have not found a single offending comparative statement. That is not a basis for a federal lawsuit.

I would just briefly like to address two points where I think there was some confusion in the causation area.

One, the Court will be most familiar with the Coumadin case, and briefly, our position is that is a fundamentally different factual situation than the one here.

In the Coumadin case, there was one branded product being challenged by one generic competitor. And the manufacturer of the branded product directly attacked the generic as not being equivalent to its product.

And so in that antitrust context, where the one

manufacturer had a monopoly and was directly attacking the one potential competitor, there were allegations sufficient to support an inference of causation.

We don't have that remotely in this case. We have no allegation of monopolies. We have multiple products in the same space. We have no ability for an inference about what the alternative would be. There are half a dozen products, at least, in this market. So Coumadin is not helpful.

The other case that plaintiff drew the Court's attention to this morning was Desiano, and that is remarkable and deserves a brief mention here.

Desiano is a Second Circuit decision, Judge Calabrase for the Panel, and it's about causation. It's a case where third-party payers alleged that they wouldn't have put Rezulin on their formularies if they had known about the safety risks that they alleged the manufacturer disguised.

The manufacturer said, Well, third-party payers don't have standing because they didn't suffer the adverse health effects of this product that is allegedly unsafe, so they don't have standing.

Judge Calabrase, writing for the Panel, said, Wait, hold on a minute. They paid more for this drug than they would have, so they suffered an economic injury even though they weren't physically harmed, so they have standing

to raise this case, this claim.

Two things, then, follow from this.

First, in explaining why the third-party payers would have standing, Judge Calabrase used a hypothetical.

That when the Court reviews this case, as I urge the Court to do, the Court will see the hypothetical is designed to take away the issue of physical injury and create a pure economic loss fact pattern. And then he says, This fact pattern shows that they would have an economic loss, so economic loss is enough.

What he does not address is whether that fact pattern would create a viable claim for preemption purposes. The word "preemption" isn't in that case. The issue is not addressed. And his hypothetical fact pattern would be a fact pattern that would be squarely preempted by the Buckman case because it's a fact pattern about fraud on the FDA. It's a hypothetical for a different purpose.

Secondly, if the Court looks at, I believe it's Footnote 9 of Desiano, the Court will see the kinds of allegations that the third-party payers made in that Rezulin litigation that were relevant to causation. Those are precisely the kind of allegations that are entirely absent from the complaint in this case.

Unless the Court has further questions...

THE COURT: No. Thank you very much.

MR. HADDAD: Thank you, your Honor.

MR. SOBOL: May I have just a moment, your Honor?

THE COURT: You may.

MR. SOBOL: First, your Honor, with respect to the argument that somehow approval of a 40-milligram dosage of Nexium in some way means that there's a superiority claim in the implicit or somewhere underlying in the FDA approval, again, that's the kind of leap of faith that AstraZeneca would want one to make from a record, but completely contrary to the allegations in the complaint.

There would be a variety of reasons why it is the FDA might think that a 40-miligram dosage of Nexium, which has absent a certain isomer that is present in Prilosec, might be necessary for it to be more effective than a placebo. A variety of other reasons, but it does not mean that one then jumps the gun and think that the FDA did a complete turnaround of what the conclusions are that are made in the underlying record and their rejection of the claim being made by the sponsor, the absence on the label of the claim that was made by the sponsor of superiority. If anything, again, the conclusion that is made on the basis of these allegations is that it's the exact opposite.

Second, I honestly don't know whether we've given up or still adopt the omission theory because I don't know

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what the defendants intend by the omission theory.

This case is based upon affirmative statements of fact and failures to state things because they're their voluntary business decision to go into the marketplace for the broad-based campaign of superiority put them in a situation where they were making claims and telling half truths or full truths, and that's what the case is about.

And so I don't know, you know, this notion that we are not required to say, you know, the word, the additional words that you should have been saying in order to correct things. We're saying that what you did, that what you said is wrong, was a false and deceptive act under the Delaware Consumer Protection Act, and that's enough.

The allegations of the complaint do have and do contain express comparative statements. We point to the fact that even in AstraZeneca's 2000 annual report, when they're launching the Nexium effort, they say that Nexium is the, on Page 2 of my slides, your Honor, Nexium is the first PPI to offer significant clinical improvements over Losec, that's the British brand name, in terms of acid control, clinical efficacy. They're saying that it was shown in studies involving 30,000 people performed in 20 countries across the world, that it's expected to establish a new, improved treatment standard in the PPI class and that Nexium

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is more effective.

These are statements being made by AstraZeneca, quite clearly evidencing the corporate decision that there is going to be a superiority and that the effort that -- the overall business objectives of this company going forward and the expenditure of hundreds of millions of dollars are going to be improving that as the basis to do the differentiation.

The next slide, your Honor, at Page 3, I, again, I point to allegations in the complaint, not just to parsing those specific advertisements that obviously have gone through the legal, you know, review at AstraZeneca, but also looking at the massive detailing efforts that were undertaken and the representations that were being made to doctors as to why Nexium was better.

So there are some of express efforts made to you about distinctions between Nexium and Prilosec. And, again, to the extent that the comparisons are implicit, then they are precisely the fodder of a Consumer Protection Act. It is not the case that we let a company deceive consumers, deceive doctors based upon, you know, a campaign that they know is intended to make claims of superiority. You really can't find those words in it. It's just not the case in the consumer protection law.

And there's also a common sense approach here,

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your Honor. If you look at these ads, and we know just what's out there in the marketplace, who's kidding who? Of course, the overall business objectives were to position Nexium as a brand better than Prilosec. That was their whole mission: Brand positioning. And what they tried to do was brand position Nexium as better than Prilosec contrary to the science, contrary to the evidence, contrary to the FDA. And that's what's going on here. And it is not appropriate on a 12(b)(6) motion to try to have a Court so narrowly construe a Consumer Protection Act as to defy common sense. That's what the Consumer Protection Act is.

Who's kidding who? Common sense. You know what they were doing here. That's what the allegations had. We should be able to proceed forward and be tested on the evidence at summary judgment.

Thank you.

THE COURT: Is the claim of superiority that you are claiming, the alleged claim of superiority matter, maybe that's the best way of saying it, the dosage, the 40 milligrams approved over the 20, or is it the actual drug?

MR. SOBOL: The way this advertising campaign went forward is: Nexium is better than Prilosec, spend your money on Nexium.

This is not a double- dose case. We do not have

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to show that they should have been doing anything else. What we are saying is what they did, in fact, was false and misleading. Nexium is better than Prilosec. And that's not true. And the FDA has said it and Tom Scully said it and our allegations allege it.

THE COURT: All right. Thank you.

MR. SOBOL: Thank you.

THE COURT: Since it is the defendants' motion, I will always give them the last word.

Anything further?

MR. HADDAD: I appreciate your Honor's generosity and I will just make one final point.

The plaintiffs' complaint concedes several places that the studies that were submitted to the FDA included studies that showed that Nexium was better than Prilosec, more effective at treating erosive esophagitis. Just one example is Paragraph 58, but they're all cited in the complaint, in our briefs.

So it's not fair, I think, to say that the theory of the complaint is that there's no difference between these two compounds. It's there in the complaint. The FDA did approve precisely what the plaintiffs say is a game, a higher dose of Nexium that shows more effectiveness at healing erosive esophagitis. That is what the FDA did, and plaintiffs want to litigate something that they feel is in

the air, that everybody knows that a new drug was positioned as better than an old drug.

But when the FDA approves a new drug, approves it based on studies that support a higher dosage because they were shown to be more effective at healing, a company is clearly permitted under federal law to announce that new drug, be proud of it, say that it's new, say that it's powerful, say that it heals the indications for which it is approved to heal, encourage patients to talk to their doctor about it. That is what the law permits. That is what the First Amendment permits. And absent some specific comparative statement or other factual statement in an ad to which this complaint has failed entirely to point that could be said to be outside the scope of the label, there's simply nothing to litigate.

THE COURT: In the last comments, plaintiffs' counsel wasn't pointing to ads, they were pointing to public disclosures as in the SEC statement. How does that fall into the scheme of things?

MR. HADDAD: Your Honor, they've pointed to one statement in an annual report from the year 2000, prior to the launch of Nexium, which I believe is described in the complaint as launching in 2001. But, in all events, it was a statement in an annual report. There's no allegation that any plaintiff or anybody saw this annual report. Their point

is, Well, this shows the company's attitude towards its product, but the annual report predates the FDA approval and the launch materials and the introduction of the product, and what they really need to litigate if they want to litigate something, our position is they have to litigate the ads.

They have decided we've discussed this in the briefs, and they have not cited any authority that says you can attack an entire DTC advertising campaign because of something you said in an annual report prior to the campaign.

THE COURT: All right. Thank you very much, counsel. We'll do our best to get something out to you promptly.

(Counsel respond, "Thank you, your Honor.")

(Court recessed at 11:35 a.m.)

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